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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,831	08/02/2001	Brigitte Bathe	211736US0X	7640

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,831

Applicant(s)

BATHE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Claims 1-33 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-7 and 16, drawn to polynucleotides encoding a transcription activator metR (SEQ ID NO:2) and coryneform bacteria host cells thereof, classified in class 435, subclass 252.32.
 - II. Claims 1-7 and 16, drawn to polynucleotides encoding an O-succinylhomoserine sulphydrylase metZ (SEQ ID NO:3) and coryneform bacteria host cells thereof, classified in class 435, subclass 252.32.
 - III. Claim 8, drawn to coryneform bacteria with an attenuated metR gene, classified in class 435, subclass 252.1.
 - IV. Claim 8, drawn to coryneform bacteria with an attenuated metZ gene, classified in class 435, subclass 252.1.
 - V. Claims 9-15 and 17-18, drawn to methods for the fermentative preparation of L-amino acids using metR, classified in class 435, subclass 113.
 - VI. Claims 9-15 and 17-18, drawn to methods for the fermentative preparation of L-amino acids using metZ, classified in class 435, subclass 113.
 - VII. Claims 19-30, drawn to methods for preparing L-methionine-containing animal feedstuffs additive, classified in class 426, subclass 54.

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VIII. Claims 31-32, drawn to animal feedstuffs additive, classified in class 426, subclass 53.

IX. Claim 33, drawn to process for obtaining RNA, cDNA, or DNA related to metR, classified in class 435, subclass 6.

X. Claim 33, drawn to process for obtaining RNA, cDNA, or DNA related to metZ, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related to each other as nucleic acids encoding proteins involved in methionine biosynthesis. However, these nucleic acids encode proteins which each have distinct functional properties catalyzing and/or affecting unique reactions in the biosynthetic pathway of methionine. Furthermore, these nucleic acids encode proteins having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus between the Groups. Thus, Groups I and II are patentably distinct. While these Groups are identically classified, to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

Groups III and IV are related to each other by virtue of the metR and metZ sequences, each attenuated in the distinct Groups, both encoding methionine biosynthesis proteins, wherein these proteins are similarly useful. However, these Groups are distinct from each other for the reasons noted above for Groups I and II.

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Groups V and VI are related to each other by virtue of the metR and metZ sequences, each used in methods of producing methionine in the distinct Groups, both encoding methionine biosynthesis proteins, wherein these proteins are similarly useful. However, these Groups are distinct from each other for the reasons noted above for Groups I and II.

Groups IX and X are related to each other by virtue of the metR and metZ sequences, each used in the methods of obtaining similar DNA in the distinct Groups, both encoding methionine biosynthesis proteins, wherein these proteins are similarly useful. However, these Groups are distinct from each other for the reasons noted above for Groups I and II.

Groups I and II are related to Groups III and IV by virtue of the fact that the met sequences in Groups I and II are attenuated in the coryneform bacteria in Groups III and IV. However, the lack of these sequences in Groups III and IV renders them wholly distinct from the sequences themselves, in Groups I and II, both structurally and functionally. Thus, Groups I and II are patentably distinct from Groups III and IV. Additionally, the search for the absence of sequences is wholly distinct from the search for those exact sequences. Thus, to examine, for example, Groups I and III, would require two distinct searches placing a search burden on the Examiner to be examined together.

Groups I and II are related to Groups V and VI because the sequences attenuated in the bacteria used in the methods of Groups V and VI are the nucleic acid sequences of Groups I and II. However, the methods use host cells with the ABSENCE of the products of Groups I and II; the products of Groups I and II are not required for the practice of the methods. Thus, Groups I and II are patentably distinct from Groups V and VI.

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Groups I and II are related to Group VII by virtue of the fact that the nucleic acid sequences of Groups I and II are methionine biosynthesis proteins and the methods of Group VII require microorganisms that produce methionine. However, the methods of Group VII do not require the use of the nucleic acid sequences of Groups I and II. Thus, Groups I and II are patentably distinct from Group VII.

Groups I and II are related to Group VIII by virtue of the fact that the nucleic acid sequences of Groups I and II are methionine biosynthesis proteins and the product of Group VIII contains methionine. However, the products of Group VIII do not require the use of the nucleic acid sequences of Groups I and II for their production, and the products of Group VIII are structurally and functionally distinct from the nucleic acid sequences of Groups I and II. Thus, Groups I and II are patentably distinct from Group VIII.

Groups I and II are related to Groups IX and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the metR or metZ nucleic acid sequences can be used for a materially distinct process of using the product, such as in the recombinant expression of the encoded protein. Thus, Groups I and II are patentably distinct from Groups IX and X.

Groups III and IV are related to Groups V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the coryneform cells with attenuated metR or metZ genes can be used for a materially distinct process of using the product, such as in the production of animal feedstuff additives. Thus, Groups III and IV are patentably distinct from Groups V and VI.

Groups III and IV are related to Group VII by virtue of the fact that the attenuated nucleic acid sequences in the coryneform bacteria of Groups III and IV are methionine biosynthesis proteins and the methods of Group VII require microorganisms that produce methionine, an example of such microorganisms being Groups III and/or IV. However, the methods of Group VII do not REQUIRE the use of the coryneform bacteria of Groups III and IV. Thus, Groups III and IV are patentably distinct from Group VII.

Groups III and IV are related to Group VIII by virtue of the fact that the attenuated nucleic acid sequences in the coryneform bacteria of Groups III and IV encoded methionine biosynthesis proteins and the product of Group VIII contains methionine. However, the products of Group VIII do not require the use of coryneform bacteria of Groups III and IV for their production, and the products of Group VIII are structurally and functionally distinct from the coryneform bacteria of Groups III and IV. Thus, Groups III and IV are patentably distinct from Group VIII.

Groups III and IV are related to the methods of Groups IX and X because the attenuated nucleic acid sequences in the coryneform bacteria of Groups III and IV are used in the methods of Groups IX and X. However, the host cells of Groups III and IV cannot be used in the methods of Groups IX and X because they do not contain the hybridizing polynucleotide required for the

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practice of Groups IX and X. Thus, Groups III and IV are patentably distinct from Groups IX and X.

The methods of Groups V and VI are related to the methods of Groups VII, IX, and X by virtue of the metR and metZ sequences. However, the methods each use distinct method steps with distinct reagents to produce different products. Thus, Groups V and VI are patentably distinct from Groups VII, IX, and X.

The methods of Groups V and VI are related to the products of Group VIII by virtue of the methionine biosynthesis nucleic acid sequences attenuated in the methods of Groups V and VI, wherein the products of Group VIII contain methionine. However, the methods neither use nor produce the products of Group VIII. Thus, Groups V and VI are patentably distinct from Group VIII.

Groups VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the additive of Group VIII can be made by drying any fermentation broth since 100% of the biomass can be removed prior to drying. Thus, Groups VII and VIII are patentably distinct.

The methods of Groups VII are related to the methods of Groups IX and X by virtue of the metR and metZ sequences. However, the methods each use distinct method steps with distinct reagents to produce different products. Thus, Group VII is patentably distinct from Groups IX and X.

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The products of Group VIII are unrelated to the methods of Groups IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the different inventions are in no way proposed as being used together. Thus, Group VIII is patentably distinct from Groups IX and X.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Groups I or II are found directed to an allowable product, then process claims in Group IX or X, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Also, if product claims in Groups III or IV are found directed to an allowable product, then process claims in Groups V or VI would now be rejoined; and if product claims in Groups VIII were found directed to an allowable product, then process claims in Groups VII would now be rejoined. . Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Rejoinder Summary

<u>Allowable Product</u>	<u>Rejoin</u>
Group I or II	Group IX or X
Group III or IV	Group V or VI
Group VIII	Group VII

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Election

5. A telephone call was made to Daniel Pereira on April 7, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

April 7, 2003

